

## **REMARKS/ARGUMENTS**

This is a submission accompanying an RCE and serves as a response to the Final Office Action dated February 1, 2006 and to the Advisory Action issued April 12, 2006 in connection with the above-identified application. A Petition for Extension of Time (one month) and the fee therefor are enclosed.

The Final Office Action has been carefully considered. Claims 10-24 are pending in the present application with Claims 10, 16, 18, 19 and 24 in independent form. Claim 16 has been amended to further clarify the features of the present application and claim 19 has been amended to correct a minor typographical error. Several additional new claims have been added in the application. Reconsideration of the application is respectfully requested.

In the Final Rejection, claims 10, 12-14, 16, 18 and 19 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by Avitall (5,555,883).

This Amendment substantially follows the previously filed Amendment which the Examiner has refused to enter and which the applicant is now resubmitting with several additional claims and additional comments.

According to Avitall (col. 6, lines 20-24), it is clear that pull wires 24 and 26 (inserted through a catheter shaft 18) are provided for the deflection of a loop segment. Likewise, according to col. 6, lines 43-46, it is understood that control wires are used for side-to-side deflection of the loop. Col. 6, lines 46-50 disclose that any desired degree of offset can be employed in the loop using the control wires.

The above referenced prior art text makes it clear to a person skilled in the art that the structure of Avitall involves and requires operating the pull wires or the control wires to deform the loop.

In contrast, the structure defined by the independent claims of the present application is such that the loop is tilted and extended due to a built-in "returning force". The claimed structure is different from the method and structure of the prior art, which involves controlling the extending of the direction of the loop by operating the pull wires and control wires which is disclosed in Avitall.

Avitall does not suggest changing the extending direction of the loop “due to a returning force” which is one of the features of the present application.

More specifically, in the present application, the loop is formed when the treatment section is extended, that is, when it is pulled out from the opening of the sheath. When the loop is pulled from the sheath, its central axis becomes tilted relative to the central axis of the elongated actuator naturally (that is, without external force being applied). Claims 10, 19 and amended claim 16 highlight this feature by specifying that the elastic deformation is due to a “returning force”. Claim 18 similarly specifies that the loop central axis of the loop is “naturally tilted.”

The Examiner contends that Avitall discloses a sheath 52, an actuating member 18, a through-hole 76 and a naturally tilted wire deployable loop. In particular, the Examiner indicates that elements 120 and 162 of Avitall are naturally tilted wire deployable loops. Applicant respectfully disagrees.

Avitall, as understood by Applicant, relates to a cardiac arrhythmia mapping and ablation catheter that is provided with a loop-shaped mapping and ablation system attached to its distal end which loop is optionally adjustable or of relatively fixed shape which can be resumed upon deployment.

In particular, Fig. 6b of Avitall discloses an embodiment of the catheter in which control wires 124 and 126 are offset 90 degrees from the conductor bundles 138 and 140. The control wires 124 and 126 are used for side to side deflection of the loop 120 as is illustrated in Figs. 6b and 6c of Avitall. Thus, the loop 120 of Avitall is not tilted naturally, rather, the tilting of the loop 120 is the result of tension provided by pulling on control wires 124 and 126. See Avitall, column 6, lines 39-51.

Further, Fig. 7a of Avitall illustrates additional configurations of the catheter. In particular, Figs. 7a and 7b are intended to illustrate a fixed shape concept. Fig. 7A illustrates an embodiment of a catheter in which the short distal working catheter sections 158, 160 may be preformed as straight sections, as illustrated by section 160, or may be preformed as curves, as illustrated in section 158. See Avitall, Column 8, lines 10-30. However, in Fig. 7A, the central

axis of the loop 162 is not tilted “against the central axis of the actuating member.” In contrast the central axis of loop 162 in Avitall is parallel to the central axis of the catheter.

Further, in response to Applicant’s arguments and previous response, the Examiner contends that Avitall discloses nitinol/shape memory loops amongst other elastic materials in columns 10, lines 1-7 which anticipate the Applicant’s claim language regarding a loop susceptible to a returning force or a loop with an elastic deformable portion. Applicant respectfully disagrees.

As noted above, in the present application, the loop is tilted naturally relative to the central axis of the actuating member when it is extended from the opening. While Avitall may disclose shape memory loops, as is noted above, Avitall fails to disclose a loop which is tilted relative to the central axis of the actuating member due to a returning force and/or a loop that is naturally tilted relative to the central axis of the actuating member. Instead, as is noted above, Avitall requires control wires to provide an outside force to tilt the loop relative to the central axis of the catheter. Further, while sections of the catheter in Avitall may be provided with a preformed curve, the loop in such an embodiment is not tilted with respect to the central axis of the catheter.

Accordingly, it is respectfully submitted that the independent claims 10, 16, 18 and 19, and any claims depending therefrom, are patentable over the cited art for at least the reasons noted above.

Claims 11, 15 and 17 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Avitall in view of Ellis, et. al. (6,093,185), or Laufer, et. al. (6,283,988) or Chia, et. al. (5,897,554). Reconsideration of this rejection is respectfully requested,

Claims 11 and 15 depend from independent claim 10 and claim 17 depends from independent claim 16. As noted above, it is respectfully submitted that claims 10 and 16 are patentable over Avitall for at least the reasons described above. Further, it is respectfully submitted that claims 10 and 16 are patentable over Avitall in view of any of Ellis, Laufer and/or Chia, because these references, either alone or in combination, fail to show or suggest the patentable features of claim 1 as described above.

Accordingly, it is respectfully submitted that claim 10, and the claims depending therefrom, including claims 11 and 15, are patentable over the cited art for at least the reasons described above. Similarly, it is respectfully submitted that claim 16, and the claims depending therefrom, including claim 17, are patentable over the cited art for at least the reasons mentioned above.

In light of the remarks and amendments made herein, it is respectfully submitted that claims 10-19 of the present application are patentable over the cited art and are in condition for allowance. Further, the foregoing remarks are applicable to newly introduced claims 20-23, which depend on the prior claims, and to newly presented independent claim 24, as well. Favorable reconsideration of the present application is respectfully requested.

Accordingly, the Examiner is respectfully requested to reconsider the application, allow the claims as amended and pass this case to issue.

EXPRESS MAIL CERTIFICATE

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail to Addressee (mail label #EV606197510US) in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on May 31, 2006

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Name of Person Mailing Correspondence



Signature

May 31, 2006

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